

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

applicant's or agent's file reference	FOR FURTHER ACTION See Not Prelimin	tification of Transmittal of International nary Examination Report (Form PCT/IPEA/416)
HSM-LUP-937 International application No.	International filing date (day/month/year)	Priority date (day/month/year) 29.10.2002
OCTAN 03/00345	27.10.2003	
nternational Patent Classification (IPC)	or both national classification and IFC	
Applicant LUPIN LIMITED et al.		
<ol> <li>This international preliminary Authority and is transmitted t</li> </ol>	examination report has been prepared by the applicant according to Article 36.	this international Fromman
TITE DEPORT consists of a	total of 4 sheets, including this cover sheet	t.
This report is also accepted been amended and are (see Rule 70.16 and S	ompanied by ANNEXES, i.e. sheets of the companied by ANNEXES, i.e. sheets of the ether that the sheets core the basis for the Administrative Instruction fection 607 of the Administrative Instruction	description, claims and/or drawings which have ntaining rectifications made before this Authority as under the PCT).
These annexes consist of a		
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Basis of the op		•
	nent of opinion with regard to novelty, inver	ntive step and industrial applicability
III   Non-establishn	nent of opinion with regard to novely,	l'a de l'idea
IV ☐ Lack of unity o	IV Lack of unity of invention Lack of unity of invention Lack of unity of inventive step or industrial applicability;	
citations and e	xpianations support	
VI ☐ Certain docum	ents cited	· · · · · · · · · · · · · · · · · ·
VII   Certain defect	: in the international application	
_	s in the international application	•
VIII □ Certain obser	vations on the international application	,
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VIII □ Certain obser	vations on the international application	ompletion of this report
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Date of submission of the demand  24.05.2004  Name and mailing address of the preliminary examining authority:	Date of continue international application  Date of continue international  Authorized	ed Officer
Date of submission of the demand  24.05.2004  Name and mailing address of the preliminary examining authority:  European Patent Company Augist	Date of continue of the international application  Date of continue of the international office  Office  Grassi,	ed Officer

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IN 03/00345

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)		Claims Claims	1-18 19
Inventive step (IS)		Claims Claims	1-18 19
Industrial applicability (IA)	Yes: No:	Claims Claims	1-19

2. Citations and explanations

see separate sheet

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6. Additional observations, if necessary:

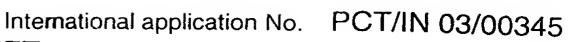
International application No.

PCT/IN 03/00345

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	Hasis	of the	renort
• •			ICOUL

1.	the	With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):				
	De	scription, Pages				
	1-2	26	as originally filed			
	Cla	aims, Numbers				
	1-1	9	as originally filed			
lai	Wit lan	th regard to the <b>lang</b> guage in which the in	uage, all the elements marked above were available or furnished to this Authority in the atternational application was filed, unless otherwise indicated under this item.			
	The	ese elements were a	vailable or furnished to this Authority in the following language: , which is:			
		the language of a ti	ranslation furnished for the purposes of the international search (under Rule 23.1(b)).			
			olication of the international application (under Rule 48.3(b)).			
		the language of a to Rule 55.2 and/or 55	anslation furnished for the purposes of international preliminary examination (under 5.3).			
3. W.	Wit inte	h regard to any <b>nucl</b> ernational preliminary	eotide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:			
		contained in the inte	ernational application in written form.			
		filed together with the international application in computer readable form.				
		furnished subseque	ntly to this Authority in written form.			
		furnished subsequently to this Authority in computer readable form.				
		The statement that in the international a	the subsequently furnished written sequence listing does not go beyond the disclosure application as filed has been furnished.			
		The statement that listing has been furn	the information recorded in computer readable form is identical to the written sequence nished.			
4. The		amendments have	resulted in the cancellation of:			
		the description,	pages:			
		the claims,	Nos.:			
		the drawings,	sheets:			
5. 🗆		This report has been been considered to	n established as if (some of) the amendments had not been made, since they have go beyond the disclosure as filed (Rule 70.2(c)).			
		(Any replacement si report.)	heet containing such amendments must be referred to under item 1 and annexed to this			

## INTERNATIONAL PRELIMINARY Inte



1) Reference is made to the following documents:

D1: US-A-4937330

D2: Chemical Abstracts, Accession No. 2001:606938 (Zhu et al., Zhongguo Yiyao Gongye Zazhi, "Synthesis of ceftiofur" (2001), 32(6), 241-242)

- The subject-matter of present claims 19 is not new (Article 33(2) PCT). In example 2 of D1 (see also claim 3) the HCl salt of ceftiofur is neutralized with PVP in aqueous THF and filtered to give the free amine (or free acid) in aqueous THF. The said solution is then added to an excess of sodium-ethyl hexanoate in aqueous THF. In view of the fact that sodium-ethyl hexanoate is the reactant and can also be regarded as organic base, the subject-matter of present claim 19 is not novel (the claim 19 does neither specify that the organic base is different from sodium-ethyl hexanoate nor that the transformation is a two-step procedure).
- 3) The subject-matter of present claims 1-18 is new (Article 33(2) PCT; cf. below).
- 4) The subject-matter of claims 1-18 involves an inventive step (Article 33(3) PCT).

D2 represents the closest prior art and discloses the preparation of ceftiofur from the same starting materials as the present application.

The present claim 1 differs from the process of D2 in that the reaction medium comprises water.

The technical problem underlying the present application is seen in the provision of an improved method for manufacture of ceftiofur (cf. page 1, lines 3/4, of the application).

In view of the fact that the applicant has submitted comparative data showing that the claimed process represents an improvement over D2, inventive activity can be acknowledged (letter of 15.10.04).